DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
% Orlando Tadeo, Jr.
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

March 19, 2015

Re: K150003
Trade/Device Name: Aquilion LB, TSX-201A/3, V6.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 30, 2014
Received: January 2, 2015

Dear Mr. Tadeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150003

Device Name

Aquilion LB, TSX-201A/3, V6.0

Indications for Use *(Describe)*

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k) SUMMARY

1. **SUBMITTER'S NAME:**
   Toshiba Medical Systems Corporation
   1385 Shimoishigami
   Otawara-Shi, Tochigi-ken, Japan 324-8550

2. **OFFICIAL CORRESPONDENT:**
   Akinori Hatanaka
   Senior Manager, Regulatory Affairs and Vigilance

3. **ESTABLISHMENT REGISTRATION:**
   9614698

4. **CONTACT PERSON:**
   Orlando Tadeo, Jr.
   Manager, Regulatory Affairs
   Toshiba America Medical Systems, Inc
   2441 Michelle Drive
   Tustin, CA 92780
   (714) 669-7459

5. **Date Prepared:**
   December 30, 2014 (Updated March 18, 2015)

6. **TRADE NAME(S):**
   Aquilion LB, TSX-201A/3, V6.0

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750, Computed Tomography X-ray System)

9. **PRODUCT CODE / DESCRIPTION:**
   90JAK / Computed Tomography X-Ray System

10. PERFORMANCE STANDARD:

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR, Subchapter J, Part 1020]

11. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aquilion LB Triton, TSX-201A/2, v4.91	Toshiba America Medical Systems	K123500	May 2, 2013

12. REASON FOR SUBMISSION:

Modification of a cleared device

13. DEVICE DESCRIPTION:

The **Aquilion LB, TSX-201A/3, v6.0** is a 40-row CT System that is intended to acquire and display cross-sectional volumes of the whole body, including the head. This system is based upon the technology and materials of previously marketed Toshiba CT systems.

14. INDICATIONS FOR USE:

This device is indicated to acquire and display cross-sectional volumes of the whole body, to include the head.

The Aquilion has the capability to provide volume sets. These volume sets can be used to perform specialized studies, using indicated software/hardware, by a trained and qualified physician.

15. SUBSTANTIAL EQUIVALENCE:

The subject device is substantially equivalent to the Aquilion LB Triton, TSX-201A/2, v4.91, K123500, marketed by Toshiba America Medical Systems. The **Aquilion LB, TSX-201A/3, v6.0**, incorporates modifications to the cleared device which include implementation of a new detector that meets the specifications of the current detector and addition of a previously cleared optional software feature. The method of operation and manufacturing process for the Aquilion LB remain unchanged from the cleared device.

A complete comparison table is included in this submission. See below for a brief summary of changes from Aquilion LB Triton, TSX-201A/2, v4.91:

Item	**Aquilion LB TSX-201A/3, v6.0**	**Aquilion LB Triton TSX-201A/2, v4.91**
510(k) Number	This submission	K123500
Detector	994 channels x 40 rows	994 channels x 40 rows
Number of detector elements	16 x 0.5 mm rows	16 x 0.5 mm rows
Console Operating System	Microsoft Windows 7	Microsoft Windows XP

Previously cleared software options being implemented to the modified device:

Lung Volume Analysis	Previously cleared per K113715

16. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the following standards IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-4, IEC60601-1-6, IEC60601-2-28, IEC60601-2-32, IEC60601-2-44, IEC60825-1, IEC62304, IEC62366, NEMA PS 3.1-3.18, NEMA XR-25 and NEMA XR-26. Additionally, this device complies with all applicable requirements of the radiation safety performance standards, as outlined in 21 CFR §1010 and §1020.

17. TESTING

Risk analysis and verification/validation testing conducted through bench testing are included in this submission which demonstrates that the requirements for the modifications made to the system have been met. The modified system was evaluated to assess detector sensitivity and noise properties (including standard deviation of noise) which demonstrated improvement in both studies.

Additional image quality metrics, utilizing phantoms, were conducted to validate that the subject device is substantially equivalent to the predicate device with regard to spatial resolution, CT number and contrast-to-noise ratio and uniformity performance.

The algorithm for Lung Volume Analysis, a system independent post processing software application that uses standard non-contrast enhanced chest volume (helical) acquisitions, has not been changed since clearance under K133715. As previously demonstrated through the use of an electronic phantom, LungMan Phantom and image data sets of the chest, this software accurately displays volume calculations. Integration testing was conducted to verify that this application functions as intended on the Aquilion LB system.

Representative diagnostic images, reviewed by an American Board Certified Radiologist, including brain, chest, abdomen and peripheral exams were also obtained using the subject device which demonstrates that the device produces images of diagnostic quality and; therefore, performs as intended.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and CT Systems.

18. CONCLUSION

The modifications incorporated into the **Aquilion LB, TSX-201A/3, v6.0** do not change the indications for use or the intended use of the device. Based upon bench testing, representative clinical images, successful completion of software validation and application of risk management and design controls, it is concluded that the subject device is safe and effective for its intended use.